

REMARKS

Upon entry of the above amendments, this application will contain claims 1, 2, 5-15, 17, 18, 20-37, 40, 41, 44-47, 50-52, 54, 56, and 58 pending and under consideration. In this submission, claim 52 has been amended, and claim 19 has been canceled. In view of the discussion below, it is believed that the application is allowable over the cited art. Consequently, reconsideration leading to allowance of all pending claims is requested.

Rejections Under 35 USC §102

Claims 1-7, 9-13, 18, 19, 40, 41, 44-47, 50, 51, and 58 were rejected under 35 USC §102(b) over Zdeblick et al. (US 5,669,909, "Zdeblick").¹ The Applicants maintain their prior assertion that Zdeblick does not disclose or make obvious the presently claimed invention directed to an interbody fusion spacer, comprising an elongated, cylindrical body as recited in the independent claims 1, 40, and 46. The implant of Zdeblick is not a cylindrical implant, but rather a conical or tapered implant. (Zdeblick, col. 5, lines 40-43; col. 7 lines 11-24; and Figures 2-8, 10, 11, 13c, and 13d.) In the latest Office Action, it was stated in response to the Applicants' previous remarks:

"[I]t is noted that to be cylindrical, at least within a broadest reasonable interpretation, the implant need only relate to or resemble a cylinder, or a generally circular shape extruded to form a solid, and need not have any other specific characteristics with respect to this limitation. Here the implant in fact is such a cylinder or at least more closely resembles or relates to the same than it does a cone, since a cone shape would need to continue to a pointed end. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc., v. Ficosa North America Corp.*, 63, USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp v. Laitram Corp.*, 60, USPQ2d 1851, 1865 (Fed. Cir. 2001) and MPEP 2211.01." (Office Action, page 6.)

From the passage above, it appears that it was determined that (1) the Zdeblick implant has a cylindrical shape or (2) that the Applicants' use of the term "cylindrical" is sufficiently broad to include a cone shape. Both of these propositions fail. First, there were no references to any citations or drawings in the Zdeblick patent that describe the Zdeblick implant as cylindrical. Rather, it appears the drawings illustrating the Zdeblick implant were reviewed; then based upon

¹ Claim 19 has been canceled. Therefore the rejection of this claim is moot.

that review it was determined that the implant's cone shape was "close enough" to a cylindrical shape. There is no support cited for the proposition that a cone is required to continue to a pointed end. Exactness is a hallmark of the patenting process. This was touched on when it was noted in the Office Action that definitions in the specification must be explicit; and reasonable clear, deliberate, and precise. With this the Applicants can agree. However, it is equally imperative that the Patent Office also be explicit, clear, and precise. "Close enough", simply put, is not close enough. The Zdeblick implant is illustrated and described as a conical implant to maintain normal curvature of the spine. (Zdeblick, col. 2, line 63-col. 3, line 29.)

Similarly, the second proposition fails. The Applicants disagree that the plain meaning of a cylindrical shape can also include a cone shape. No authority was cited for the proposition that a cylindrical shape can include within its broadest definition a cone shape. Admittedly, in limited circumstances, an examiner can rely upon common knowledge in making a rejection. (MPEP 2144.03) However, it is believed that this is not a case that falls within the limited circumstances. Further, it is believed that the Federal courts have not indorsed the proposition in the Office Action. (See, Skinner v. Dow Chemical Co., 85 USPQ 191, 194, and 196 (CCPA 1950) (the court held that the plaintiff's (Skinner's) die for extruding aluminum was distinguishable over the prior art references stating: "Skinner taught the art several things, ... (d) That the mixing opening through the female die form must be cylindrical rather than conical or funnel shape ... (e) that the mixing chamber formed must be cylindrical--that is it must have parallel instead of conical or funnel-like walls.") See also Modern Products Supply Co. v. Drachenberg, 68 USPQ 10, 14 (CCPA 1945) (the court referring to the expert's testimony in support of its ruling: "The Drachenberg chute, which is cylindrical and eccentrically disposed with reference to the cutting disc, plaintiff's expert stated is not the mechanical equivalent of Jenkin's conical wall.")).

If the Examiner maintains this rejection the Applicants respectfully request that the Examiner provide authority supporting the proposition maintained in the Office Action pursuant to MPEP 2144.03.C.

When the Zdeblick patent is reviewed as a whole it actually teaches away from using a cylindrical implant. The Zdeblick patent teaches that a conical implant is used rather than a cylindrical implant to maintain the normal spinal curvature. (Id, col. 2, line 63 -col. 3, line 29.) Zdeblick consider singly or in combination with the other references of record do not make the

claimed invention obvious. In light of the above discussion, withdrawal of the rejections of claims 1-7, 9-13, 18, 40, 41, 44-47, 50, 51, and 58 over Zdeblick is respectfully requested.

Claims 52 and 54-57 were rejected under §102(b) over Brosnahan (US 5,645,598, “Brosnahan”). Independent claim 52 has been amended to recite that an opening in the concave surface provides communication with the interior cavity. Support for this amendment can be found in the Application in Figs. 1, 2, and 7 as well as in other locations in the Application. Therefore it is believed that this amendment does not add any new matter. It is acknowledged that amendments are not entered after a final rejection as a matter of right. However, it is believed that this amendment will place the Application in condition for allowance and that no further searching will be required by the Examiner. Entry of this amendment is respectfully requested.

It is believed that independent claim 52 is patentable over Brosnahan. Brosnahan does not disclose or make obvious an implant that includes an opening in the concave side wall to allow access to an interior chamber. This opening allows a surgeon to load the interior of the implant with an osteogenic material either prior to or after implantation of the implant into the prepared disc space. This feature is neither disclosed nor contemplated by Brosnahan. Withdrawal of the rejection is therefore requested for claim 52 and for claims 54-57, which depend from claim 52.

Claim 19 was rejected under 35 USC §102(e) over Kohrs (US 6,224,631, “Kohrs”). Claim 19 has been cancelled. Therefore this rejection is moot.

Rejections under 35 USC §103

Claims 1-15, 17-37, 40, 41, 44-47, 50, 51, and 58 were rejected under §103(a) over Zdeblick in view of Michelson (US 5,593,409, “Michelson”).² The Applicants respectfully traverse this rejection. Zdeblick has been discussed above. It should be noted that Zdeblick teaches away from the claimed invention. Zdeblick describes and illustrates a conical implant. The shape of the implant is provided to maintain the curvature of the spine. (Zdeblick, Figs. 13(C, D); 14 (C, D); col. 2, line 63-col. 3, line 29; and col. 12, lines 7-12). Zdeblick teaches that cylindrical implants require over reaming of the posterior portion of the vertebrae, do not restore

² Claim 19 has been canceled. Therefore the rejection of this claim is moot.

the lordotic curvature, and likely cause kyphotic deformity. (Id, col. 3, lines 10-20.) Michelson discloses a spinal fusion implant that is at least partly cylindrical--the type of implant that Zdeblick teaches against using. In light of the above, it is maintained that Michelson should not be combined with the teaching of Zdeblick. Therefore, withdrawal of the rejections of claims 1-15, 17-37, 40, 41, 44-47, 50, 51, and 58 is requested.

CONCLUSION

In view of the foregoing discussion, reconsideration, withdrawal of all outstanding rejections, and allowance of this application containing claims 1, 2, 5-15, 17, 18, 20-37, 40, 41, 44-47, 50-52, 54, 56, and 58 are respectfully requested. In addition, the Examiner is invited to telephone the undersigned attorney if there are any questions about this submission or other formal matters, which may be addressed in that fashion to facilitate allowance of this application.

Respectfully submitted,

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